

Medicare Medical Policy

Salivary Hormone Testing

MEDICARE MEDICAL POLICY NUMBER: 54

Effective Date: 7/1/2024	MEDICARE COVERAGE CRITERIA	2
Last Review Date: 6/2024	POLICY CROSS REFERENCES.....	2
Next Annual Review: 9/2024	POLICY GUIDELINES.....	3
	REGULATORY STATUS.....	3
	BILLING GUIDELINES AND CODING	3
	REFERENCES.....	5
	POLICY REVISION HISTORY.....	5

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Salivary Hormone Testing	<p>Local Coverage Determination (LCD): Measurement of Salivary Hormones (L36857)</p> <p>NOTE: According to this LCD, “Noridian Healthcare Solutions currently considers salivary cortisol collected in the evening for diagnosis of Cushing’s syndrome as the only medically necessary and reasonable hormone measurement from salivary fluid. All other determinations of salivary hormones (e.g., thyroid, testosterone, estrogen, parathyroid, growth hormone, etc.) are considered investigational.” This will apply to any salivary hormone testing, regardless of CPT or HCPCS used. Services which lack scientific evidence regarding safety and efficacy because they are investigational are considered to be “not medically reasonable or necessary” for Medicare Plan members. (<i>Medicare Claims Processing Manual, Ch. 23, §30 A</i>)</p>

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

None

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See the associated local coverage article (LCA) for related billing and coding guidance:

- LCA: Billing and Coding: Measurement of Salivary Hormones ([A57613](#))
- According to LCA A57613, “[b]ecause current CPT® codes do not specify or identify “salivary” hormone testing from serum or urine hormone testing, claims for salivary levels of hormone should be coded with NOS code 84999 and the words ‘salivary cortisol’. For other than cortisol use ‘salivary (name of other hormone)’ which will generate a denial.”

HCPCS CODES S3650 AND S3652

HCPCS codes S3650 and S3652 are considered “not medically necessary” under this policy. However, like all S-codes, the *National Physician Fee Schedule Relative Value File (NPF SRVF)*, which is published by the Centers for Medicare and Medicaid Services (CMS)¹, indicates HCPCS codes S3650 and S3652 have been assigned a Status Indicator of “I.” This is defined as “Not valid for Medicare purposes.” In addition, HCPCS codes S3650 and S3652 are not recognized as valid codes for claim submission as indicated in the relevant Company Coding Policy (*HCPCS S-Codes and H-Codes, 22.0*). Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
CPT	0462U	Melatonin levels test, sleep study, 7 or 9 sample melatonin profile (cortisol optional), enzyme-linked immunosorbent assay (ELISA), saliva, screening/preliminary (<i>Used to report the Salimetrics® Salivary Melatonin Profile (Circadian Phase Assessment) test by Salimetrics® Clinical Laboratory/Salimetrics LLC.</i>)

	82530	Cortisol; free
	82533	Cortisol; total
	82626	Dehydroepiandrosterone (DHEA)
	82627	Dehydroepiandrosterone-sulfate (DHEA-S)
	82670	Estradiol
	82671	Estrogens; fractionated
	82672	Estrogens; total
	82677	Estriol
	82679	Estrone
	82681	Estradiol; free, direct measurement (eg, equilibrium dialysis)
	83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
	83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
	84144	Progesterone
	84402	Testosterone; free
	84403	Testosterone; total
	84436	Thyroxine; total
	84439	Thyroxine; free
	84443	Thyroid stimulating hormone (TSH)
	84479	Thyroid hormone (T3 or T4) uptake or thyroid hormone binding ratio (THBR)
	84480	Triiodothyronine T3; total (TT-3)
	84999	Unlisted chemistry procedure
	86316	Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each
	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
	88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure
HCPCS	S3650	Saliva test, hormone level; during menopause (CMS-assigned Status "I" code – See "Billing Guidelines")
	S3652	Saliva test, hormone level; to assess preterm labor risk (CMS-assigned Status "I" code – See "Billing Guidelines")

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.

- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	Annual review (converted to new format 2/2023)
10/2023	Annual review; no changes to criteria
7/2024	Q3 2024 Code updates